K024230

Summary of Safety and Effectiveness
Liquichek™ ANA Controls Set, Positive: Homogeneous, Speckled, Centromere, and Nucleolar Patterns

1.0 Submitter

JAN 15 2003

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Date of Summary Preparation

December 20, 2002

2.0 Device Identification

Product Trade Name:	Liquichek™ ANA Controls Set, Positive: Homogeneous, Speckled, Centromere, and Nucleolar Patterns
Common Name:	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control
Classifications:	Class II
Product Code:	82DHN
Regulation Number:	21 CFR 866.5100

3.0 Device to Which Substantial Equivalence is Claimed

I. Kallestad™ ANA Positive Control Homogeneous Pattern
Bio-Rad Laboratories

510 (k) Number: K792610

II. Liquichek™ ANA Control, Centromere Pattern
Bio-Rad Laboratories

510 (k) Number: K984397

III. Kallestad™ Autoantibody Positive Control
Bio-Rad Laboratories

510 (k) Number: K792610

4.0 Description of Device

These products are prepared from human serum with added preservatives. These controls are provided in liquid form for convenience

5.0 Statement of Intended Use

The new Liquichek™ ANA Controls Set, Positive: Homogeneous, Speckled, Centromere, and Nucleolar Patterns, is intended for use as an unassayed quality control set to monitor indirect immunofluorescent testing of antinuclear antibodies (ANA).

6.0 Comparison of the new device with the Predicate Device

The controls in the set are substantially equivalent to the following quality control materials for autoimmune analyses that is currently in the market:

I. Kallestad™ ANA Positive Control Homogeneous Pattern
Bio-Rad Laboratories

510 (k) Number: K792610

II. Liquichek™ ANA Control, Centromere Pattern
Bio-Rad Laboratories

510 (k) Number: K984397

III. Kallestad™ Autoantibody Positive Control
Bio-Rad Laboratories

510 (k) Number: K792610

Tables 1-3 (below) contains comparison information of similarities and differences between the new Liquichek™ ANA Controls Set, Positive: Homogeneous, Speckled, Centromere, and Nucleolar Patterns and the currently Kallestad™ ANA Positive Control Homogeneous Pattern, Liquichek™ ANA Control, Centromere Pattern, and Kallestad™ Autoantibody Positive Control to which substantial equivalence is claimed.

Table 1. Similarities and Differences between new and predicate device Liquichek™ ANA Controls Set, Positive: Homogeneous, Speckled, Centromere, and Nucleolar Patterns and Kallestad™ ANA Positive Control Homogeneous Pattern

Characteristics	Liquichek™ ANA Controls Set, Positive: Homogeneous, Speckled, Centromere, and Nucleolar Patterns (New Device)	Kallestad™ ANA Positive Control Homogeneous Pattern (Predicate Device)
	Similarities	
Intended Use	The Liquichek ANA Controls Set, Positive: Homogeneous, Speckled, Centromere, and Nucleolar Patterns, is intended for use as an unassayed quality control set to monitor indirect immunofluorescent testing of antinuclear antibodies (ANA).	The intended use of the ANA Positive Control Homogeneous Pattern is the quality control of indirect fluorescent antibody procedures for the detection and semi-quantitation of human autoantibodies to nuclear antigens (ANA).
Matrix	Human Serum	Human Serum
Storage (Unopened)	2°C to 8°C until expiration date	2°C to 8°C until expiration date
Form	Liquid	Liquid
	Differences	
Stability (Opened)	Once opened the analytes will be stable for 60 days.	No claim for stability
Packaging	1 vial of each single analyte control	Single analyte control
Analyte	ANA Homogeneous Pattern ANA Centromere Pattern ANA Speckled Pattern ANA Nucleolar Pattern	ANA Homogeneous Pattern

Table 2. Similarities and Differences between new and predicate device

Liquichek™ ANA Controls Set, Positive: Homogeneous, Speckled, Centromere, and Nucleolar Patterns and Liquichek™ ANA Control, Centromere Pattern

Characteristics	Liquichek™ ANA Controls Set, Positive: Homogeneous, Speckled, Centromere, and Nucleolar Patterns (New Device)	Liquichek™ ANA Control, Centromere Pattern (Predicate Device)
	Similarities	
Intended Use	The Liquichek ANA Controls Set, Positive: Homogeneous, Speckled, Centromere, and Nucleolar Patterns, is intended for use as an unassayed quality control set to monitor indirect immunofluorescent testing of antinuclear antibodies (ANA).	The Liquichek™ ANA Control, Centromere Pattern is intended for use as an unassayed quality control to monitor indirect immunofluorescent testing of antinuclear antibodies (ANA).
Matrix	Human Serum	Human Serum
Storage (Unopened)	2°C to 8°C until expiration date	2°C to 8°C until expiration date
Form	Liquid	Liquid
	Differences	
Stability (Opened)	Once opened the analytes will be stable for 60 days.	Once opened the analyte will be stable for 30 days.
Packaging	1 vial of each single analyte control	Single analyte control
Analyte	ANA Homogeneous Pattern ANA Centromere Pattern ANA Speckled Pattern ANA Nucleolar Pattern	ANA Centromere Pattern

Table 3. Similarities and Differences between new and predicate device

Liquichek™ ANA Controls Set, Positive: Homogeneous, Speckled, Centromere, and Nucleolar Patterns and Kallestad™ Autoantibody Positive Control

Characteristics	Liquichek™ ANA Controls Set, Positive: Homogeneous, Speckled, Centromere, and Nucleolar Patterns (New Device)	Kallestad™ Autoantibody Positive Control (Predicate Device)
	Similarities	
Intended Use	The Liquichek ANA Controls Set, Positive: Homogeneous, Speckled, Centromere, and Nucleolar Patterns, is intended for use as an unassayed quality control set to monitor indirect immunofluorescent testing of antinuclear antibodies (ANA).	The Autoantibody Positive Control is a replacement reagent in the Kallestad Fluorescent Autoantibody test with mouse kidney, mouse stomach/kidney, Hep-2 cell line, or Crithidia luciliae substrates.
Matrix	Human Serum	Human Serum
Storage (Unopened)	2°C to 8°C until expiration date	2°C to 8°C until expiration date
Form	Liquid	Liquid
	Differences	
Stability (Opened)	Once opened the analytes will be stable for 60 days.	No claim for stability
Packaging	1 vial of each single analyte control	Single analyte control
Analyte	ANA Homogeneous Pattern ANA Centromere Pattern ANA Speckled Pattern ANA Nucleolar Pattern	ANA: Centromere Pattern, SSA, SSB, Scl-70, Sm, RNP, Spindle Pattern, Nucleolar Pattern AMA ASMA APCA Anti-nDNA

7.0 Summary of Performance Data

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek™ ANA Controls Set, Positive: Homogeneous, Speckled, Centromere, and Nucleolar Patterns. Product claims are as follows:

7.1 Once the controls are opened the analytes will be stable for 60 days when stored tightly capped at 2 to 8°C.

7.2 The control is stable for 2 years when stored unopened at 2 - 8°C.

Real time studies will be ongoing to support the shelf life of this product.

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 1 5 2003

Ms. Yvette Lloyd
Senior Regulatory Affairs Specialist
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine, CA 92618-2017

Re: k024230
Trade/Device Name: Liquichek™ ANA Controls Set, Positive: Homogeneous, Speckled, Centromere, and Nucleolar Patterns
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear antibody immunological test system
Regulatory Class: Class II
Product Code: DHN
Dated: December 20, 2002
Received: December 23, 2002

Dear Ms. Lloyd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K024230

Device Name: **Liquichek ANA Controls Set, Positive: Homogeneous, Speckled, Centromere, and Nucleolar Patterns**

Indications for Use:

The Liquichek ANA Controls Set, Positive: Homogeneous, Speckled, Centromere, and Nucleolar Patterns, is intended for use as an unassayed quality control set to monitor indirect immunofluorescent testing of antinuclear antibodies (ANA).

(PLEASE DO NOT WRITE BELOW THE LINE-CONINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ✓ or Over-the Counter use _____

J P Reeves for J. Bautista

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K024230